

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Amel AMBLARD

Title: ADJUSTMENT OF THE ATRIAL SENSITIVITY IN AN ACTIVE
IMPLANTABLE MEDICAL DEVICE SUCH AS CARDIAC
PACEMAKER

Serial No.: 10/645,326

Filed: August 21, 2003

Art Unit: 3762

Examiner: George Robert Evanisko

Confirmation: 7566

Mailing Date of: March 18, 2008
Office Action

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. 1.132

I, Dr Philippe Mabo, declare that:

1. I am Professor of Cardiology at the University Hospital of Rennes, France (since 1992), Chief of the department of Cardiology and Vascular Diseases (since 2004), Director of the electrophysiology laboratory (since 1998) and of the Research Centre on Technological Innovations (since 2008), involved in basic and clinical research in the field of cardiac arrhythmias and implantable devices for 25 years. I have extensive experience and knowledge regarding both the technical and functional aspect of the diagnosis and treatment of cardiac

rhythm disorders, including treatment of heartbeat rate disorders with devices that are capable of automatic mode commutation. I have personal knowledge of the facts stated in this declaration or have confirmed the accuracy of same through review of documents and/or discussions with others. Although English is not my native language, I read and write in the English language without need for a translator.

2. I am not an employee of Ela Medical or Sorin Group, however I have been working as a consultant as part of missions in collaboration with Ela Medical and involved in many clinical studies relating to the evaluation of new medical devices of Ela Medical's since 1995. I am not being compensated in connection with my preparation of this declaration. No part of my compensation is dependant upon the outcome of this patent application.

3. I am familiar with the United States Patent Application No. 10/645,326, which I understand also is referred to as "Ela 163B" and "Gestion Capteur" and with the Official Action dated March 18, 2008.

4. This declaration is being submitted to respond to the Examiner's statement in the Official Action that the Gestion Capteur specification did not reasonably convey to a person skilled in the art, at the time the application was filed, "'means for preventing switching to a DDD pacing mode when a condition indicative of a suspected loss of atrial detection is detected' and corresponding method step of 'in order to prevent inappropriate switching to a DDD pacing mode'" (Action, p. 2)

5. I respectfully disagree with the Examiner's comments quoted above, and with the Examiner's comments as follows: "Nowhere does the specification describe a 'means for preventing switching to a DDD pacing mode. . . ' and ' . . .when a condition indicative of a suspected atrial detection is detected'" (Action, p. 2-3)

6. In my experience, a person of ordinary skill in the art in this technical field would be a person having an education in electrical engineering, biomedical engineering, or medicine, and a few years work with dual chamber cardiac pacing devices in the field of diagnosing cardiac rate disorders. Such a person skilled in the art would understand that a dual chamber pacemaker capable of automatic mode commutation would have algorithms that can control the mode switching, for example, to or from a DDD pacing mode.

7. In my opinion, the Gestion Capteur patent specification does indeed disclose to a person of ordinary skill in the art both a "means for avoiding inappropriate switching to a DDD

pacing mode” and “when a condition indicative of a suspected loss of atrial detection is detected”. I initially note, that the specification specifically teaches avoiding inappropriate switching to a DDD pacing mode when a condition indicative of a suspected loss of atrial detection is detected: “[I]t is an object of the invention to improve the auto-adjustment of the sensitivity and the stimulation energy values, suitable to avoid inopportune and useless misadjustments of these parameters. Broadly, the present invention concerns improved apparatus and signal processing methods that detect situations of atrial under-detection and loss of atrial capture, to be able to ensure the correct operation of the various algorithms operating the device. One aspect of the invention is directed to a device that is equipped with an automatic commutation operation, in which the detection and correction of the defects of atrial capture or under-detection are employed to avoid an inappropriate switching to operating in a conventional DDD operating mode. This avoids unnecessarily stimulating the ventricle, and thus mitigates the possible noxious effects, from the hemodynamic point of view, of delivering such an inappropriate therapy.” Specification, page 2, line 15 through page 3, line 4.

8. The specification provides a means to avoid inappropriate stimulation when atrial under-detection is detected: “Advantageously, the suspecting means also is able to deliver an atrial counter-stimulation of relatively increased energy, in the event of an absence of ventricular activity post-atrial stimulation. This delivery may actually occur indirectly, that is, by controlling the appropriate stimulation to deliver a stimulation pulse at the desired energy level as the counter-stimulation pulse.” Specification, page 4, lines 1-5.

9. The specification provides a specific example of how inappropriate stimulation is avoided: “If the atrial activity is systematically a stimulated activity (Stimulation A), the device initially suspect a loss of atrial capture. In this case, the energy of the following stimulation is increased, with the parameterized value (maximum energy or an energy corresponding to a step above the current energy). Then, if the normal atrio-ventricular conduction delay is restored (the upper chronogram of Fig. 2), the device returns to its initial operation mode AAI, without AVD, with an increased stimulation energy.” Specification, page 9, lines 12-17. Further, the specification teaches three cases of managing a loss of atrial detection. In these cases, if the device suspects a loss of atrial detection, the device increases atrial sensitivity. This is a step taken to prevent switching to a DDD pacing mode. See page 10, line 19 through page 11, line 19 and Figs. 4 and 5.

10. In my opinion, a person of ordinary skill in the art at the time the application was filed in August 2003 would know from Applicant's disclosure in the specification, based on their training and experience, that if a cardiac device suspects a loss of atrial detection, the cardiac device can avoid inappropriate switching to a DDD pacing mode. Therefore, in my opinion, Applicant's specification does in fact reasonably convey to a person having ordinary skill in the art "means for avoiding inappropriate switching to a DDD pacing mode when a condition indicative of a suspected loss of atrial detection is detected" and I respectfully disagree with the Examiner's statement to the contrary.

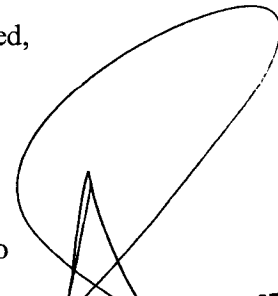
11. I have read and concur with the advantages to the invention set forth in the patent application and in the response to the Examiner's Office Action that I understand is being filed concurrently with this Declaration. For the reasons stated above, I believe that the Gestion Capteur patent application provides a sufficient disclosure to reasonably convey to a person of ordinary skill in the relevant art, that the inventor had possession of the claimed invention at the time the application was filed as defined by the pending claims of this application.

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or any patent issuing therefrom, declares that all statements made of his own knowledge are true and that all statements made on information and belief are believed to be true.

Respectfully submitted,

Date: August 25, 2008

Name: Philippe Mabo



CHU RENNES
DÉPARTEMENT DE CARDIOLOGIE
ET MALADIES VASCULAIRES
Prof. Ph. MABO